

**FOOD AND DRUG ADMINISTRATION (FDA)
RECALLS/ALERT NOTICES**

1. FDA MEDICAL EQUIPMENT RECALLS AND ALERTS. The following recalls are reported in accordance with AFMLL 2-95, page CE-4, and should be treated as directed modifications in accordance with that AFMLL and AFI 41-201, Chapter 2, Section D. If you possess any of these items and have not received recall notification, you should contact the manufacturer for recall instructions. Suspension is only required for Class I items. (FOM, Capt David Zemkosky, DSN 343-4028)

CLASS I RECALLS: None

CLASS II RECALLS:

6515NS
MDC 12636
PRODUCT Monitor Systems, Physiologic
Solar 7000/8000 Patient Monitors with Software Version 4A, used to display physiological data from modules which monitor the patient for ECG, blood pressure etc. Recall #Z-691-7.
CODE Version 4A software, installed in Solar 7000/8000 Patient Monitors used with Solar ECG/12SL Modules.
MANUFACTURER Marquette Electronics, Inc., Milwaukee, Wisconsin.
RECALLED BY Manufacturer, by letter dated July 7, 1997. Firm-initiated field correction ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 780 Solar ECG/12SL Modules with Version 4A software were distributed. Only the Solar 7000/8000 Patient Monitors used with the Solar ECG/12SL Modules are affected, and the software in these monitors is to be replaced. Also, 83 Version 4A software upgrade kits for units at consignees were distributed.
REASON A software defect is causing incorrect waveform data.

None Present
 Action Taken _____

6520NS
MDC 11161
PRODUCT Handpieces, Dental
Non-Fiber Optic High Speed Dental Handpieces:
a) Catalog No. 750044, Tradition Non-Fiber Optic Handpiece with conventional chuck (with wrench)
b) Catalog No. 780044, Traditional L Non-fiber Optic Handpiece with Power Lever chuck (wrenchless).
Recall Z-674/675-7.
CODE All with date code E127 through E227.
MANUFACTURER Midwest Dental Products (Dentsply), Des Plaines, Illinois.
RECALLED BY Manufacturer, by letter dated May 29, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and China.
QUANTITY 444 handpieces were distributed.
REASON Some of the hand pieces may have loose fitting water spray tubes which may fall out during use, and be swallowed or aspirated.

None Present
 Action Taken _____

6515NS
MDC 11474
PRODUCT Electromyographs
Advantage EMG System, Model A100, an electromyogram device used to measure and record electrical activity associated with skeletal muscle. Recall #Z-687-7.
CODE All serial numbers.
MANUFACTURER Advantage Medical, London, Ontario, Canada.
RECALLED BY Manufacturer, by letter dated May 12, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and Canada.
QUANTITY 89 units were distributed.
REASON The device could cause an electrical burn to the patient.

PRODUCT Cathcor Remote 20 Inch Monitor, used with Siemens Cathcor System, an ECG recording device. Recall #Z-740-7.
CODE Part numbers 61-61-942 and 08-99-019. All units.
MANUFACTURER Siemens-Elema AB, Life Support Systems Division, Solna, Sweden.
RECALLED BY Siemens Medical Systems, Inc., Danvers, Massachusetts, by letter on November 5, 1996. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY Undetermined.
REASON The monitor used in a cardiac catheterization disconnected from the base pedestal and fell, causing injury.

None Present
 Action Taken _____

6515NS
MDC 15065
PRODUCT Suture Units, Automatic
Premium Multifire TA (Stapler):
a) Premium Multifire TA 30-V3 (stapler), Order Code 010315
b) Premium Multifire TA 60-3.5 (stapler), Order Code: 010317
c) Premium Multifire TA 60-4.8 (stapler), Order Code: 010319.
Recall #Z-684/686-7.
CODE Lot numbers:
a) N6E33, N6E283, N6F91, N6G37, N6H97, N6K55, N6M132, N6M137, N6M232, N6M248, N6G189, N6J06;
b) N6E47, N6E68, N6E303, N6F88, N6F166, N6G88, N6G127, N6H09, N6H84, N6H94, N6H138, N6J19, N6F68, N6J171, N6J217, N6F160, N6K116, N6K186, N6K205, N6M172, N6M269, N7A53, N6F226, N6J186
c) N6E125, N6F116, N6F178, N6G113, N6H22, N6J30, N6J35F, N6J243, N6K145, N6K175, N6M188, N7A30.
MANUFACTURER United States Surgical Corporation, Norwalk, Connecticut.
RECALLED BY Manufacturer, by letter dated April 17, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 41,180 units were distributed.
REASON The jaws of the devices may fail to open upon firing a staple, which can result in tissue damage to the patient.

None Present
 Action Taken _____

6680NS
MDC 11748
PRODUCT Flowmeter, Gas
Precision Medical Flowmeters, used to provide a metered dose of oxygen to patients in the hospital environment:
a) Product No. 2MFA1008
b) Product No. 2MFA1008C
c) Product No. 2MFA1008PTO
d) Product No. D2MFA1008
e) Product No. D2MFA1008C
f) Product No. Y2MFA1008
g) Product No. Y2MFA1008C.
Recall #Z-698/704-7.

CODE Date codes from 395 to 397.
MANUFACTURER Precision Medical, Northampton, Pennsylvania.
RECALLED BY Manufacturer, by letter dated March 19, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY Approximately 2,691 devices were distributed.
REASON The devices may catch on fire during use in high flow situations (10LPM and greater) when mounted to hospital Puritan-Bennett wall outlets.

None Present
 Action Taken _____

6515NS
MDC 14360
PRODUCT Ventilators, Respirators
Model No 2800 Portable Ventilator for delivery of gas to patients dependent on artificial respiration. Recall #Z-672-7.

CODE All units.
MANUFACTURER Nellcor Puritan Bennett, Carlsbad, California.
RECALLED BY Manufacturer, by letter dated August 16, 1996. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 4,500 units were distributed.
REASON The High Pressure Alarm does not sound if set a 57 or 60 cm. of water, and the Pressure Relief Valves may stick in the closed position.

None Present
 Action Taken _____

6525NS
MDC 16599
PRODUCT Tables, Nuclear Medicing (Scanning)
Vision FX Series Nuclear Imaging System Patient Table. Recall #Z-683-7.
CODE Serial numbers: 93-96, 100-173, P2, PP3.
MANUFACTURER SMV America, Twinsburg, Ohio.
RECALLED BY Manufacturer, by visit. Firm-initiated field correction ongoing.
DISTRIBUTION Nationwide, Puerto Rico, France, Guatemala.
QUANTITY 79 systems were distributed.
REASON The fasteners, used to assemble the motorized patient table, were inappropriate for the proper functioning of the device.

None Present
 Action Taken _____

6525NS
MDC 13271
PRODUCT X-Ray Rad Units, Fixed
Diagnostic X-Ray System - SuperStand, for general purpose radiography:
a) Model No. WWT0100 XRT Table;
b) Model No. WWT0101 XRT Table;
c) Model No. WWT0200 XRT Table;
d) Model No. WWT0201 XRT Table;
e) Model No. WWT0300 XRT Table.
Recall #Z-634/638-7.

CODE None.
MANUFACTURER Wuestec Medical, Inc., Mobile, Alabama.
RECALLED BY Manufacturer. FDA approved the firm's corrective action plan on June 2, 1997. Firm-initiated field correction ongoing.
DISTRIBUTION Nationwide.
QUANTITY Undetermined.
REASON The diagnostic x-ray devices were found noncompliant with 21 CFR 1020.30(n) of the Federal Performance Standard for Diagnostic X-Ray System and Their Major Components.

None Present
 Action Taken _____

6525NS
MDC 15944
PRODUCT Camera, Gamma
Vision FX Series Digital Nuclear Imaging systems, used to produce tomographic images of the body which can aid in the diagnosis of ailments such as cancer and heart disease:
a) Model FX-40;
b) Model FX-80.
Recall #Z-626/627-7.

CODE Serial numbers 93-96, 100-173, P2, and PP3. All vision FX series model numbers are affected.
MANUFACTURER SMV America, Twinsburg, Ohio.
RECALLED BY Manufacturer, by letter on March 19, 1997. Firm-initiated field correction ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 79 units were distributed.
REASON The collimator of the devices was sliding off the collimator server because it was difficult for the operator to determine when the collimator was properly engaged on the collimator server. This falling collimator problem may result in potential injuries to the operator and/or patient.

None Present
 Action Taken _____

6515NS
MDC 12636
PRODUCT Monitor Systems, Physiologic
AL-800PA SpO2 Module, used with the Nihon Kohden Multi-Parameter Patient Monitor, for pulseoxymetry monitoring in patients. Recall #Z-631-7.

CODE All modules bearing serial number 06354 and below.
MANUFACTURER Nihon Kohden, Inc., Irvine, California.
RECALLED BY Manufacturer, by letter dated January 24, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 3,109 units were distributed.

REASON Crosstalk (noise) between the LED driver circuit and the SpO2 sensing circuit is due to spatial limitations of the printed circuit board layout which caused an increase of the SpO2 sensing circuit offset current to give incorrect readings.

None Present
 Action Taken _____

6525NS
MDC 13271
PRODUCT

X-Ray Rad Units, Fixed
Diagnostic X-Ray System - CompuGen Systems, used for general purpose radiography:
(a) Model No. WWG0301 X-Ray Control Console;
(b) Model No. WWG0302 Power Unit;
(c) Model No. WWG0303 High Voltage Generator;
(d) Model No. WWG0310 Under/Over Power Unit;
(e) Model No. WWG4001 X-Ray Control Console;
(f) Model No. WWG4002 Power Unit;
(g) Model No. WWG4003 High Voltage Generator;
(h) Model No. WWG4010 Under/Over Power Unit;
(i) Model No. WWG0351 X-Ray Control (50 hz);
(j) Model No. WWG0352 Power Unit (50 hz);
(k) Model No. WWG0350 Under/Over Power Unit (50 hz);
(l) Model No. WWG4051 X-Ray Control Console (50 hz);
(m) Model No. WWG4052 Power Unit (50 hz);
(n) Model No. WWG4050 Under/Over Power Unit (50 hz).
Recall #Z-517/530-7.

CODE See Model numbers above.
MANUFACTURER Wuestec Medical, Inc., Mobile, Alabama.
RECALLED BY Manufacturer. FDA approved the firm's corrective action plan on May 9, 1997. Firm-initiated field correction ongoing.

DISTRIBUTION Nationwide.
QUANTITY All units manufactured prior to March 26, 1996.
REASON The diagnostic x-ray devices were found noncompliant with 21 CFR 1010.2 AND 1010.3 of the Federal Performance Standard for Diagnostic X-Ray System and Their Major Components. Some of the devices were improperly identified and certified to the diagnostic x-ray standard.

None Present
 Action Taken _____

6525NS
MDC 13272
PRODUCT

X-Ray Rad Units, Mobile
Mobile Radiographic Systems, intended for portable use in making film radiographs in a hospital environment:
(a) Lorad Model RT 125 OEM, Serial Nos. 38001-380068;
(b) Philips Model X-Ray 2000, Serial Nos. 1500496001-1500397027;
(c) Philips PRACTIX 2000;
(d) Bennet HMX (High Frequency Mobile Radiographic System), Model HMX-5, Serial Nos. 94-37-001 through 96-37-467.
Recall #Z-550/553-7.

CODE Devices manufactured prior to October 1996. (See serial numbers above).
MANUFACTURER Lorad Corporation, Danbury, Connecticut.
RECALLED BY Manufacturer, by letter on April 14, 1997. Firm-initiated field correction ongoing.
DISTRIBUTION Nationwide.

QUANTITY 70 Lorad RT 125 units; 491 Philips-200/PRACXTIX units; and 22 Bennet HMX-5 units were distributed.
REASON The radiographic units may be subject to unanticipated movement.

None Present
 Action Taken _____

6525NS
MDC 13281 Computers, Radiotherapy Planning System
PRODUCT Pinnacle Radiation Therapy Planning Software Version 2.1f. Recall #Z-565-7.
CODE None.
MANUFACTURER ADAC Laboratories, Milpitas, California.
RECALLED BY Manufacturer, by telephone, followed by letter on February 14, 1996. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 83 tapes of the software version 2.1f were distributed.
REASON The wedge scatter fields will be calculated incorrectly if the wedge filter is not square. A monitor unit miscalculation of up to 12.25% is possible.

None Present
 Action Taken _____

CLASS III RECALLS:

6525NS
MDC 13281 Computers, Radiotherapy Planning System
PRODUCT Radiation Oncology Computer Systems (ROCS) Treatment Planning System Software Version 5.0.X. Recall #Z-564-7.
CODE Software version 5.0.X.
MANUFACTURER Radiation Oncology Computer Systems, Inc., Carlsbad, California.
RECALLED BY Manufacturer, by letters dated September 27, 1996, and November 6, 1996. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 248 sets of disks were distributed.
REASON An error occurs when using this software version for brachytherapy dose estimations for user specified calculation points for re-oriented linear sources.

None Present
 Action Taken _____

MEDICAL EQUIPMENT SAFETY ALERTS:

6515NS
MDC 16405 Apheresis Units
PRODUCT Haemonetics PCS Plasma Collection System. Safety Alert #N-015-7.
CODE Software versions prior to Rev. E.
MANUFACTURER Haemonetics Corporation, Braintree, Massachusetts.
ALERTED BY Manufacturer, by updating software on August 8, 1995, by fax on May 24, 1996, and by releasing revised software on June 4, 1996. Corrective action was completed in September 1996.
DISTRIBUTION Nationwide.
QUANTITY 1,776 instruments were distributed.

REASON Firm instituted a software upgrade (Revision E) to alert operators if there is a greater than 4 gram weight change in the collection bag between the end of the collection cycle and the end of the saline infusion, it could dilute the test sample which is used for viral marker testing.

None Present
 Action Taken _____

6515NS
MDC 16718 Saws, Bone, Sternal
PRODUCT 3M Sarns Sternal Saw II System, used during chest surgery. Safety Alert #N-014-7.
CODE Part #98-0702-0597-0.
MANUFACTURER 3M Health Care, Ann Arbor, Michigan.
ALERTED BY Manufacturer, by letter of April 24, 1997.
DISTRIBUTION Nationwide and international.
QUANTITY Undetermined.
REASON Use of Komet Medical's KM-278 and KM-278N blades are not to be used with the 3M Sarns Sternal Saw II System, because they are not suitable replacement for the 3M Sarns 5589 and 5755 blades, as specified by Komet Medical. These blades do not fit into the chuck properly and may not stay attached to the saw and be expelled during use.

None Present
 Action Taken _____

2. DRUG/SUPPLY PRODUCT RECALLS AND MEDICAL INFORMATION. The Food and Drug Administration (FDA) advises that the drug products listed below were recalled by the manufacturers or distributors concerned. The FDA has classified these recalls as follows:

CLASS I: A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.

CLASS II: A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

CLASS III: A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. Most of these items are nonstandard, and the possibility exists that medical activities may have purchased them locally. There is also a possibility that some of these items have NSNs assigned and may have been reported in earlier Q.A. messages. Activities having quantities of these items on hand will immediately suspend the materiel from issue and use. CONUS activities will contact the nearest office of the respective manufacturer or distributor for disposition instructions. OVERSEAS activities will report quantities suspended to AFMLO/FOM-P no later than 12 SEP 97 for disposition instructions. They should include nomenclature; lot number; manufacturer; quantity suspended; strength size; requisition; and DPSC purchase order number, contract number, and stock record account number (SRAN). (FOM-P), Bonnie Phillips, DSN (343-4170)

CLASS I RECALLS: None

CLASS II RECALLS:

NSN	6505 Nonstandard
PRODUCT	Vicodin Tablets (Hydrocodone Bitartrate 5 mg/Acetaminophen 500 mg), in bottles of 100 tablets,
Rx	indicated for the relief of moderate to moderately severe pain. Recall #D-234-7.
CODE	7604461 EXP 9/00.
MANUFACTURER	Knoll Laboratories, A Division of Knoll Pharmaceutical Company, Mount Olive, New Jersey.
RECALLED BY	Med-Pro, Inc., Lexington, Nebraska (repacker), by telephone on April 15, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Colorado.
QUANTITY 6,819 bottles were distributed.
REASON Tablet mix-up -- Some bottles of Vicodin were found to contain Trilisate Tablets (Choline magnesium trisalicylate).

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Bio-Safe Antibacterial Lotion (Triclosan 0.3%), OTC, in 8 fluid ounce bottles and 55 gallon drums. Recall #D-236-7.
CODE Lot numbers 6987 (8 ounces) and 7005 (55 gallons).
MANUFACTURER Stanford Personal Care, Saugus, California.
RECALLED BY Bio-Safe Skin Products, Milwaukie, Oregon, by telephone on June 20, 1997, and by letter sent on June 24, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY Approximately 56,000 8-ounce bottles and 4 55-gallon drums were distributed.
REASON Product is contaminated with Pseudomonas Aeruginosa.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT a) Red Blood Cells; b) Platelets; c) Recovered Plasma. Recall #B-869/871-7.
CODE Unit #28026-8571.
MANUFACTURER United Blood Services, San Angelo, Texas.
RECALLED BY Blood Systems, Inc., Scottsdale, Arizona, by letters dated February 18, 1997, and May 2, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Texas and North Carolina.
QUANTITY 1 unit of each component was distributed.
REASON Blood products tested negative for the antibody to the human immunodeficiency virus type 1 (anti-HIV-1), but were collected from a donor who previously tested repeatedly reactive for anti-HIV-1, Western blot negative.

None Present
 Action Taken _____

NSN 6505 Nonstandard

PRODUCT a) Red Blood Cells; b) Cryoprecipitated AHF;
c) Plasma; d) Recovered Plasma.
Recall #B-1046/1049-7.
CODE Unit numbers: a) 41FV24002, 41GJ37198,
41GJ37527, 41GW08651, 41GW08967, 41KC09277,
41KC09610; b) 41GJ37198, 41GJ37527;
c) 41GJ37527; d) 41FV24002, 41GJ37198,
41GW08651, 41GW08967, 41KC09277, 41KC09610,
41LG53711.
MANUFACTURER American Red Cross Blood Services, Birmingham,
Alabama.
RECALLED BY Manufacturer, by letters between April 16,
1996, and December 12, 1996. Firm-initiated
recall ongoing.
DISTRIBUTION Alabama, California, Puerto Rico.
QUANTITY a) 7 units; b) 2 units; c) 1 unit; d) 7 units
were distributed.
REASON Blood products tested negative for the
antibody to the hepatitis C virus encoded
antigen (anti-HCV), but were collected from
donors who previously tested repeatedly
reactive for anti-HCV.

[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT a) HIV-1 Western Blot Kit; b) OraSure HIV-1
Western Blot Kit. Recall #B-783/784-7.
CODE Lot numbers: a) M0613601, M0617602, M0625601,
M0709601, M0719602, M0725601, M0813601, M0814601,
M0815602, M0815603, M0910601, M0916601, M0919601,
M1004602, M1009601, M1022601, M1101604
b) M0730601, M0910602, M1016601, M1205601, M0117703.
yMANUFACTURER Epitepe, Inc., Beaverton, Oregon.
RECALLED BY Manufacturer, by letter on February 27, 1997.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY a) 3,654 kits; b) 712 kits were distributed.
REASON High positive control vials were mislabeled
as the conjugate vials for the test kits.

[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Norpace Disopyramide Phosphate Capsules, 150 mg,

in bottles of 100 and 1,000, Rx oral antiarrhythmic.
 Recall #D-182-7.
 Lot numbers: 6B75B and 6B758A EXP 2/89.
 Searle, Caguas, Puerto Rico.
 Searle, Skokie, Illinois, by letter dated
 May 8, 1997. Firm-initiated recall
 ongoing.
 Nationwide.
 9,000 100-capsule bottles and 1,668 1000-bottles
 were distributed; firm estimated that 10-25% of the
 product remained on market at time of recall
 initiation.
 Some capsules may be partially filled.

None Present
 Action Taken _____

6505 Nonstandard
 (a) Red Blood Cells; (b) Platelets.
 Recall #B-672/673-7.
 Unit numbers: 9513701, 9132464.
 Oklahoma Blood Institute, Oklahoma City, Oklahoma.
 Manufacturer, by fax on July 11, 1995 or
 August 1, 1995. Firm-initiated recall ongoing.
 Texas, Oklahoma, Pennsylvania.
 2 units of each component were distributed.
 Blood products were collected from a donor who
 emigrated from an area considered endemic for malaria.

None Present
 Action Taken _____

6505 Nonstandard
 Cytogam-(CVM-IGIV), Cytomegalovirus Immune Globulin
 Intravenous (Human).
 Recall #B-736-7.
 Unit #MV1CMV-38 Exp 8/15/97.
 Massachusetts Public Health Biologic Laboratories,
 Jamaica Plains, Massachusetts.
 Manufacturer, by letter dated May 6, 1997.
 Firm-initiated recall ongoing.
 Delaware and Maryland.
 3,677 vials were distributed.
 Immune Globulin product was found in post-release
 testing to have elevated levels of the plasma
 Pre-Kallikrein Activator (PKA).

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Various Rx drugs:
a) Benadryl (Diphenhydramine Hydrochloride Injection USP), 50 mg/ml, in 10 ml vials
b) Dilantin (Phenytoin Sodium Injection, USP), 250 mg, in 5 ml (ready/mixed) vials
c) Ketalar (Ketamine Hydrochloride Injection, USP), 50 mg/ml, in 10 ml vials
d) Ketalar (Ketamine Hydrochloride Injection, USP), 100 mg/ml, in 5 ml vials
e) Cerebyx (Fosphenytoin Sodium) Injection, 50 mg PE/ml, in 10 ml vials.
Recall #D-191/195-7.
CODE Lot numbers: a) 031N6P; b) 025N6P; c) 002N6P;
d) 032N6P; e) 01706P.
MANUFACTURER Warner-Lambert Company, Parke-Davis Sterile Products Division, Rochester, Michigan.
RECALLED BY The Parke-Davis Division of Warner-Lambert Company, Morris Plains, New Jersey, by letter on May 8, 1997. Firm-initiated recall ongoing.
DISTRIBUTION a-d) Nationwide and international; e) Georgia, Massachusetts, Ohio, Pennsylvania.
QUANTITY a) 2,897 units; b) 3,330 units; c) 1,468 units
d) 2,862 units; e) 12 units were distributed.
REASON Lack of assurance of sterility.

[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT SoloPak Metoclopramide Injection USP, 10 mg (5 mg/ml), in 2ml vials, Rx intravenous or intramuscular injection for the relief of symptoms associated with acute and recurrent diabetic gastric stasis, and for the prophylaxis of postoperative nausea and vomiting in those circumstances where nasogastric suction is undesirable.
Recall #D-197-7.
CODE Lot #960456 EXP 4/98.
MANUFACTURER Solopak Laboratories, Inc., Elk Grove Village, Illinois.
RECALLED BY Manufacturer, by letter dated June 3, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 138,050 vials were distributed; firm estimated that 1% of product remained on market at time

REASON of recall initiation.
Product exceeds in-process bulk bioburden specification.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT SoloPak Heparin Lock Flush Solution, USP, Preservative Free, 10 USP units/ml packaged in 3 ml pre-filled syringes for maintenance of patency of indwelling intravenous catheters designed for intermittent injection therapy or blood sampling and not to be used for anticoagulant therapy:

Catalog #10673: 3 ml Hy-Pod Syringe with 25G x 5/8" needle, individually wrapped, 120 per carton; Catalog #10683: 3 ml Hy-Pod Syringe, needleless individually wrapped, 120 per carton; Catalog #11773: 3 ml Hy-Pod Syringe, contained in the Lok-Pak-N Heparin Lock Flush Procedure Pack, 200 per case; Catalog #06003: 3 ml Hy-Pod Syringe, contained in the Lok-Pak Heparin Lock Flush Procedure Pack, needle not included, 200 per case. Recall #D-199-7.

CODE Syringe lot 95L008, packaged as:

Catalog #11773: lot 95L008B
Catalog #06003: lot 95L008C
Catalog #10673: lot 95L008D
Catalog #10683: lot 95L008E.

MANUFACTURER SoloPak Medical Products Inc., Franklin Park, Illinois.

RECALLED BY SoloPak Medical Products Inc., Elk Grove Village, Illinois, by letter dated May 13, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 62,212 syringes were distributed; firm estimated that 9% of the product remained on market at time of recall initiation.

REASON Subpotent (stability).

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Dilantin Infatabs (Phenytoin Tablets, USP) 50 mg, in bottles of 100 and in blister pack of 10 x 10, used in the treatment of seizures. Recall #D-209-7.

CODE Lot numbers: 07006V 10/98 (bottles of 100,
07106V 10/98 (bottles of 100), 07106VA 10/98
(blister pack of 10x10).
MANUFACTURER Warner Lambert Company, Vega Baja, Puerto
Rico.
RECALLED BY Parke-Davis, Division of Warner Lambert,
Morris Plains, New Jersey, by letter on May 9,
1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 39,647 units were distributed.
REASON Product failed dissolution testing
(stability).

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Solopak Gentamicin Sulfate Injection, USP, 80
mg/2mL (40 mg/mL), in 2 mL multiple dose
vials, Rx antibiotic. Recall #D-210-7.
CODE Lot #951218 EXP 06/97.
MANUFACTURER SoloPak Laboratories, Inc., Elk Grove Village,
Illinois.
RECALLED BY Manufacturer, by letter dated May 14, 1997.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 193,850 vials were distributed.
REASON Super-potency.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Red Blood Cells. Recall #B-671-7.
CODE Unit #6012121.
MANUFACTURER Southern Oklahoma Blood Institute, Ardmore, Oklahoma.
RECALLED BY Oklahoma Blood Institute, Oklahoma City, Oklahoma,
by telephone and fax on November 24, 1995.
Firm-initiated recall ongoing.
DISTRIBUTION New York.
QUANTITY 1 unit was distributed.
REASON Blood products were collected from a donor who
emigrated from an area considered endemic for malaria.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Clinda-Derm Clindamycin Phosphate Topical Solution USP 1%, in bottles with a net content of 60 ml, used in the treatment of acne vulgaris. Recall #D-188-7.
CODE Lot numbers: 6B6891, 6B6892, 6D6130, 6F6289, 6H6484, 6A6485, and 6L6669. All of these lots were distributed under the Clinda-Derm brand. Only lot 6H6484 also included product labeled with the h.l. Moore brand.
MANUFACTURER Paddock Laboratories, Inc., Minneapolis, Minnesota.
RECALLED BY Manufacturer, by letter on May 16, 1997, Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 36,400 vials were distributed.
REASON Bulk Clindamycin was recalled by Roussel Corporation (parent firm of Biochimica Opos) due to AADA (Abbreviated Antibiotic Drug Application) discrepancies regarding manufacturing process.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Demerol (Meperidine HCl, USP) Syrup, 10 mg/ml, in 16 ounce bottles, used for relief of moderate to severe pain. Recall #D-190-7.
CODE Lot numbers: LB323 EXP 2/98, KK361 EXP 9/97, LF369 EXP 6/98.
MANUFACTURER Bayer Corporation, Myerstown, Pennsylvania.
RECALLED BY Sanofi Pharmaceuticals, Inc., New York, New York, by letter dated April 23, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 22,203 units were distributed.
REASON Superpotent.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT a) Red Blood Cells; (b) Fresh Frozen Plasma; c) Cryoprecipitate; d) Recovered Plasma. Recall #B-856/859-7.
CODE All units collected from 9/1/91 to 11/20/96.
MANUFACTURER New York Blood Services, also known as New York Blood Center, New York.

RECALLED BY Manufacturer, by letters dated February 13 and 28, 1997, and June 16, 1997, and by letters dated February 10, 1997, and June 26, 1997.
Firm-initiated recall ongoing.
DISTRIBUTION New York, New Jersey, Switzerland.
QUANTITY 5,000 units.
REASON Blood products may have been improperly tested for viral markers between 09/1/91 and 11/20/96.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Platelets, Pheresis. Recall #B-887-7.
CODE Unit numbers: 03P98568, 03LL08317, 03LL08316.
MANUFACTURER American Red Cross Blood Services, Atlanta, Georgia.
RECALLED BY Manufacturer, by letter dated December 2, 1996.
Firm-initiated recall ongoing.
DISTRIBUTION Georgia.
QUANTITY 3 units were distributed.
REASON Blood products have unacceptable platelet yields.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT a) Fresh Frozen Plasma; b) Cryoprecipitate;
c) Recovered Plasma. Recall #B-1023/1025-7.
CODE Units collected on 8/1/96. Contact FDA, Center for
Biologics Evaluation and Research, Office of
Compliance
(301) 594-1191 for individual unit numbers recalled.
MANUFACTURER New York Blood Services, also known as New York
Blood Center, New York, New York.
RECALLED BY Manufacturer, by letters dated December 12,13, and
27, 1996. Firm-initiated recall ongoing.
DISTRIBUTION New York, New Jersey, Switzerland.
QUANTITY a) 77 units; b) 54 units; c) 53 units were
distributed.
REASON Blood products may been improperly tested (fixed
plates) for the antibody to the human immunodeficiency
virus type 1 (anti-HIV-1).

None Present
 Action Taken _____

NSN 6505 Nonstandard
 PRODUCT a) Fresh Frozen Plasma; b) Recovered Plasma.
 Recall #B-1052/1053-7.
 CODE a) 6710747 6710751 6710753
 6710682 6710704 6710716
 6710754 6710756 6710725
 6710701 6710709 6710722
 6710671 6710740 6710744
 6710749 6710757 6710673
 6710686 6710695 6710724
 6710752 6710679 6710666
 6710674 6710694 6710710
 6710681 6710718 6710720
 6710723 6710727 6710730
 6710683 6710742 6710734
 6710739 6710670 6710729
 6710741 6710685 6710705
 b) 6710743 6710746 6710748
 6710755 6710693 6710668
 6710672 6710675 6710678
 6710680 6710687 6710688
 6710689 6710690 6710731
 6710696 6710702 6710703
 6710707 6710713 6710714
 6710715 6710717 6710721
 6710733 6710737.
 MANUFACTURER New York Blood Services, also known as New York
 Blood Center, New York, New York.
 RECALLED BY Manufacturer, by letter dated February 12, 1997.
 Firm-initiated recall ongoing.
 DISTRIBUTION New York and Switzerland.
 QUANTITY a) 42 units; b) 26 units were distributed.
 REASON Blood products may have been improperly tested for the
 antigen to the human immunodeficiency virus type 1
 (HIV-1p24 Antigen).

[] None Present
 [] Action Taken _____

NSN 6505 Nonstandard
 PRODUCT Red Blood Cells. Recall #B-1075-7.
 CODE Unit #2028045.
 MANUFACTURER Lorain County Blood Bank, Inc., Elyria, Ohio.
 RECALLED BY Manufacturer, by telephone on May 30, 1996,
 followed by letter dated June 9, 1997.
 Firm-initiated recall ongoing.
 DISTRIBUTION Ohio.
 QUANTITY 1 unit was distributed.
 REASON Blood product was incorrectly tested for the antibody
 to the hepatitis B core antigen (anti-HBc).

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Pentothal (Thiopental Sodium for Injection, USP)
Ready-to-Mix Syringe Kit, 500 mg 2.5% (25 mg/ml),
used as an anesthetic. Recall #D-221-7.
CODE Kit Lot #26-652-DK.
MANUFACTURER Abbott Laboratories, Rocky Mount, North Carolina.
RECALLED BY Abbott Laboratories, Hospital Products Division,
Abbott Park, Illinois, by letter dated June 17,
1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 31,775 kits were distributed; firm estimated that
70 percent of the product remained on market at
time of recall initiation.
REASON Product is packaged in a kit that has a separate
expiration date exceeding that of the Pentothal
component expiration date.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Clindamycin Phosphate Injection, USP, 150 mg/ml;
an Rx small volume parenteral semisynthetic
antibiotic for IV or IM administration, packaged in
2 ml, 4 ml, and 6 ml single dose vials and 60 ml
bulk vials. Recall #D-222-7.
CODE List 4050 (2 ml fliptop vial): lots 08-045-DK, 09-
055-DK, 11-020-DK, 14-449-DK, 16-537-DK, 20-589-DK
List 4051 (4 ml fliptop vial): lots 07-143-DK, 08-
529-DK, 08-541-DK, 08-650-DK, 09-119-DK, 10-537-DK,
12-472-DK, 13-233-DK, 13-258-DK, 15-073-DK, 15-267-
-613-DK, 18-533-DK, 19-223,DK, 20-453-DK, 20-676-
DK, 21-188-DK, 22-451-DK, 22-682-DK, 25-023-DK, 26-
350-DK List 4052 (6 ml fliptop vial): lots 06-427-
DK, 08-383-DK, 09-108-DK, 10-448-DK, 11-293-DK, 13-
221-DK, 14-435-DK, 15-135-DK, 16-371-DK, 17-161-DK,
20-381-DK, 22-672-DK List 4053 (2 ml ADD-Vantage
vial): lots 15-245-DK, 21-166-DK, 27-276-DK List
4054 (4 ml ADD-Vantage vial): lots 12-417-DK,
13-177-DK, 15-254-DK, 15-264-DK,
16-669-DK, 18-412-DK, 19-198-DK, 19-209-DK,
20-498-DK, 20-509-DK, 21-175-DK, 22-610-DK,
24-531-DK, 25-160-DK, 26-558-DK, 27-002-DK,
27-162-DK
List 4055 (6 ml ADD-Vantage vial): 12-427-DK, 13-
164-DK, 17-016-DK, 19-220-DK, 20-521-DK, 21-184-DK,

22-600-DK, 25-024-DK, 28-588-DK
List 4197 (60 ml): 08-459-DK, 11-250-DK, 18-641-DK,
21-090-DK.

MANUFACTURER Abbott Laboratories, Rocky Mount, North Carolina.
RECALLED BY Abbott Laboratories, Hospital Products Division,
Abbott Park, Illinois, by letter dated June 20,
1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 3,262,319 vials were distributed; firm estimated
that 5 percent of product remained on market at
time recall initiation.
REASON Bulk Clindamycin was recalled by Roussel
Corporation (parent firm of Biochimica Opos) due to
AADA (Abbreviated Antibiotic Drug Application)
discrepancies regarding manufacturing process.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Thrombin - JMI Topical Thrombin, 5,000 U.S. Units
and 1,000 U.S. Units. Recall #B-922-7.
CODE Lot numbers: R114A77 (5000 US Units), R113A27,
R113A28, R113A30 (1,000 US Units)
MANUFACTURER GenTrac, Inc., subsidiary of Jones Medical
Industries, Inc., Middleton, Wisconsin.
RECALLED BY Manufacturer, by letter dated April 9, 1997.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 5,600 vials were distributed.
REASON Product failed six-month stability testing for its
labeled potency.

None Present
 Action Taken _____

NSN 6505 Nonstandard
 PRODUCT Clindamycin Phosphate Injection in 2 ml, 4 ml, 6 ml single dose vials and 60 ml and 100 ml bulk pharmacy packages. Recall #D-183-7.

CODE	SIZE (mL)	RECALLED LOT #	EXP. DATE
	2a	P6E007	11/97
	4a	P6E014	11/97
	6a	P6E007F1	11/97
	60b	P6E305*	11/97
	lot mfg. for private label Solopak Labs		
	60b	P6K318	02/98
	100b	P6E313	11/97
	100b	P6K320	02/98

a = Single dose vials
 b = Pharmacy bulk package.

MANUFACTURER Gensia Laboratories, Irvine, California.
 RECALLED BY Manufacturer, by fax on March 13, 1997.
 Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.
 QUANTITY 104,459 units were distributed. Firm estimated that 50% of product remained on market at time of recall initiation.

REASON Bulk Clindamycin was recalled by Roussel Corporation (parent firm of Biochimica Opos) due to AADA (Abbreviated Antibiotic Drug Application) discrepancies regarding manufacturing process.

None Present
 Action Taken _____

NSN 6505 Nonstandard
 PRODUCT Oxygen, USP, Rx compressed medical gas, held in T, K, S, AND, and ANE high pressure cylinders. Recall #D-212-7.

CODE Lot numbers: E42-7024, E42-7044, E42-7066, E42-7083, E42-7091, E42-7092, E42-7099.

MANUFACTURER C.S. Gases, Inc., Buffalo, New York.
 RECALLED BY Manufacturer, by telephone on May 16, 1997, followed by letter on May 19, 1997.
 Firm-initiated recall ongoing.

DISTRIBUTION New York.
 QUANTITY Approximately 127 cylinders were distributed.

REASON Failure to properly calibrate finished product testing equipment.

None Present
 Action Taken _____

NSN 6505 Nonstandard

PRODUCT Schein Pharmaceutical Procainamide Hydrochloride
Extended-Release Tablets, USP 500 mg, in bottles of
100, indicated for the treatment of documented
arrhythmias. Recall #D-213-7.
CODE Lot #D6A0204 EXP 2/98.
MANUFACTURER Danbury Pharmacal, Danbury, Connecticut.
RECALLED BY Danbury Pharmacal, Inc., Caramel, New York, by
letter on May 14, 1997. Firm-initiated recall
ongoing.
DISTRIBUTION California, Connecticut, Illinois, Florida,
Georgia, Kentucky, Massachusetts, Missouri, New
Jersey, New York, Ohio, Tennessee, Texas.
QUANTITY 1,939 bottles were distributed.
REASON Dissolution failure (stability).

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Guiatuss AC, in 1 gallon, 16 ounce, 8 ounce and 4
ounce bottles, an expectorant cough suppressant.
Recall #D-214-7.
CODE Lot numbers: QN6718, QN6719, QS6885, QB7075.
MANUFACTURER AlphaPharma, U.S. Pharmaceutical Division, Baltimore,
Maryland.
RECALLED BY Manufacturer, by letter dated April 25, 1997.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 286,944 units were distributed.
REASON Presence of precipitate.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Enplus HD Syrup (Hydrocodone Bitartrate 2.5
mg/Phenylephrine HCl 5 mg/Chlorpheniramine Maleate
2 mg), in pint bottles, used for the relief of
cough and congestion. Product is also manufactured
under the names of Efasin-HD Plus Liquid and
Echotuss-HC Syrup. Recall #D-215-7.
CODE Lot numbers: 60702 and 70108.
MANUFACTURER Elgee, Inc., Rosenberg, Texas.
RECALLED BY Manufacturer, by telephone, followed by letter on
June 9, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Georgia, Ohio, Michigan.
QUANTITY 5,010 pints of lot 60701 and 6,912 pints of lot
70108 were distributed. Firm estimated that none
of lot 60701 and 558 pints of lot 70108 remained on

REASON market at time of recall initiation.
Presence of particulate matter.

[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Bumetanide Injection, USP, 0.25 mg/ml, Rx
injectable diuretic. Recall #D-216-7.
CODE Lot #LB224 EXP 2/99.
MANUFACTURER Ben Venue Laboratories, doing business as Bedford
Laboratories, Bedford, Ohio.
RECALLED BY Manufacturer, by letter dated June 4, 1997.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 21,720 vials were distributed.
REASON Discoloration.

[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Loxitane (Loxapine Succinate) 10 mg Capsules, Rx
antidepressant, in unit dose 10 (2x5) strips and
bottles of 1,000, under the Lederle Laboratories
label. Recall D-218-7.
CODE Lot numbers: 445-787 and 445-788.
MANUFACTURER Wyeth-Ayerst/Lederle, Pearl River, New York.
RECALLED BY Wyeth-Ayerst Laboratories, Frazer, Pennsylvania,
by letter on June 11, 1997. Firm-initiated recall
ongoing.
DISTRIBUTION Oklahoma, Colorado, Texas, Tennessee, North
Carolina.
QUANTITY 4 boxes containing 100 blister packed capsules and
11 bottles of 1000 were distributed.
REASON Superpotency.

[] None Present
[] Action Taken _____

NSN 6515 Nonstandard
 PRODUCT Vacutainer brand Lok-on Needle Disposal Container, designed to lock the needle and needle holder onto the container.
 Recall #Z-462-7.
 CODE Catalog #366223, involve Lot #'s 5H602, 5H603, 5J604, 5J605, 5J606, 5K600, 5L600, 5L601, 5L602, 5M600, 6A600, 6A601, 6A602, 6C600, 6C601, 6D602, 6D603, 6E600, 6E601, 6F601.
 MANUFACTURER Becton Dickinson Vacutainer Systems, Sumter, South Carolina.
 RECALLED BY Becton Dickinson Vacutainer Systems, Franklin Lakes, New Jersey, by letters on October 21 and 31, 1996. Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide and international.
 QUANTITY 58,350 units were distributed.
 REASON The device to be adulterated in that some of the containers have been manufactured with a defective needle removal device (blue insert) which may break, causing the needle holder to permanently lock to the container.

[] None Present
 [] Action Taken _____

NSN 6515 Nonstandard
 PRODUCT GD XI Anatomically Correct Lifeline Patient Cable w/Leadwires, Model No. 14081 - Type A, an anatomically correct Lifeline Patient Cable to a Siemens 15 Pin Connector with lead wires, for ECG monitoring in general practitioner settings. Recall #Z-726-7.
 CODE Lot numbers of the cable/leadwire: C02105CH, C02504CH, and C02505CH. NOTE: The finished device kit is NOT identified with lot numbers.
 MANUFACTURER Graphic Controls Corporation, Cherry Hill, New Jersey.
 RECALLED BY Graphic Controls Corporation, Buffalo, New York, by letter dated May 16, 1997. Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide and international.
 QUANTITY 301 sets were distributed.
 REASON The lead wires were placed incorrectly into the cable, which caused the lead location to be mislabeled.

[] None Present
 [] Action Taken _____

NSN 6515 Nonstandard

PRODUCT BMW Clampless Valved Venous Catheters:
 (a) Clampless Valved Catheter-Tunneled
 (CVC-T) Catalog Nos.: CVC421 CO, CVC421 1K, CVC661
 CO,CVC661 1K, CVC961 CO, CVC961 1K;
 (b) Clampless Valved-PICC (CV-PIC) Catalog Nos.:
 PIC401 1K, PIC501 1K;
 (c) Clampless Valved Midline-Catheter (CV-MLC)
Catalog Number: MLC401 1K. Recall #Z-466/468-7.
CODE All lots.
MANUFACTURER BMW Medical Inc., Salt Lake City, Utah.
RECALLED BY Manufacturer, by letter on April 2, 1997, followed by
 fax on April 8, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Alabama, California, Colorado, Indiana, New Jersey,
 Massachusetts, Maryland, Michigan, Missouri,
 Pennsylvania, South Carolina, Texas, Washington state.
QUANTITY 53 cases (10 units per case) were distributed.
REASON The catheters have potentially defective molded female
 hubs which can result in a crack developing after
 repeated cleaning with alcohol.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Kendall Curity Spinal Anesthesia Tray, sterile,
 Reorder #4761. Recall #Z-566-7.
CODE Lot #AD8372KG.
MANUFACTURER Especialidades Medicas Kenmex, Tiajuana, Mexico.
RECALLED BY Kendall Healthcare Products Company, Mansfield,
 Massachusetts, by telephone on April 7, 1997,
 followed by letter dated April 8, 1997.
 Firm-initiated recall ongoing.
DISTRIBUTION Alabama, California, Georgia, Mississippi.
QUANTITY 310 units were distributed.
REASON The tray contained Xylocaine MPF 5% with Glucose
 7.5%, 2 ML instead of Bupivacaine Hydrochloride
 0.75 with Dextrose 8.25%, 2ML.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Sentry Medical Products Heparin-Bonded Polyurethane
 Umbilical Vessel Catheters and Trays with Catheters:
 (a) 3.5 F Heparin-Bonded Polyurethane Catheter,
 Reorder Nos. 15000350 and MC0040;
 (b) 5.0 F Heparin-Bonded Polyurethane Catheter,
 Reorder Nos. 1500500 and MC00050;

(c) Insertion Tray with Catheter (3.5 F),
 Reorder Nos. 1502350 and MT00010;
 (d) Insertion Tray with Catheter (5.0 F),
 Reorder Nos. 1502500 and MT00020.
 Recall #Z-567/570-7.

CODE	Sentry	LTP	Sentry	LTP
	p/n	p/n	lot #	lot #
1500350		MC0040	056649	904641
			056413	904640
			055544	904478
			056695	904764
			055554	904697
1500500		MC00050	055553	904731
			055559	904765
			057396	904826
			055550	904639
			055549	904636
1502350		MT00010	055525	904444
			056764	904698
			056414	904763
			055555	904699
			055556	904724
1502500		MT00020	055556	904725
			055560	904761
			057213	904829.

MANUFACTURER RECALLED BY Kendall Sheridan, Argle, New York.
 Ludlow Technical Products, Chicopee,
 Massachusetts, by telephone on April 15, 1997,
 followed by letter issued April 24, 1997.
 Firm-initiated recall ongoing.

DISTRIBUTION QUANTITY Nationwide.
 245 cases were distributed.
 REASON The lumens of the catheters are occluded by
 Benzalkonium Heparin Coating and cannot flush
 correctly.

[] None Present
 [] Action Taken _____

NSN 6515 Nonstandard
 PRODUCT A.T.S. reusable Cylindrical Tourniquet Cuffs, used
 to exert enough pressure on the arterial blood flow
 within a limb to produce a bloodless operating
 field: a) DPSB ATS Cuffs; b) SPSB ATS Cuffs;
 c) DPDB ATS Cuffs; d) SPDB ATS Cuffs.
 Recall #Z-679-682-7.

CODE	a) DPSB ATS Cuffs:
Catalog No.	Size(in): Lot No:
60-7500-001-00	8 91867200, 91825800
60-7500-002-00	12 91874800, 91840700, 91811900

60-7500-003-00	18	91880200, 91862800, 91843500, 91830000
60-7500-004-00	24	91859400, 91822900, 91836600, 91889900
60-7500-005-00	30	91894100, 91862900, 91836700
60-7500-006-00	34	91902800, 91900100, 91880300, 91859500, 91836800, 91823600
60-7500-007-00	42	91885500, 91863000, 91836900;

b) SPSB ATS Cuffs:

60-7600-001-00	8	91900400, 91837100
60-7600-002-00	12	91885600, 91837200
60-7600-003-00	18	91900500, 91880400, 918455600
60-7600-004-00	24	91875000, 91840800
60-7600-005-00	30	91885700
60-7600-006-00	34	91885800, 91867300, 91840900, 91826100
60-7600-007-00	42	91885900, 91841000;

c) DPDB ATS Cuffs:

60-7555-001-00	12	91872000, 91825900
60-7555-002-00	18	91837000, 91874900, 91859600
60-7555-003-00	24	91872100, 91855500;

d) SPDB ATS Cuffs:

60-7666-002-00	18	91875100, 91841100
60-7666-003-00	24	91867400.

MANUFACTURER Zimmer Patient Care Division, Statesville, North Carolina.

RECALLED BY Zimmer Patient Care Division, Dover, Ohio, by letters on May 23 and 30, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and international.

QUANTITY 9,564 cuffs were distributed; firm estimated that 90% remained on market at time of recall initiation.

REASON The cuff has the potential to deflate due to breakage or cracking of the tourniquet port where is welded to the cuff bladder material

[] None Present
 [] Action Taken _____

NSN 6515 Nonstandard

PRODUCT ProView Self Sealing Sterilization Pouch, used to contain items during sterilization.

Recall #Z-661-7.
CODE Product #PM5410, Lot #6312.
MANUFACTURER Cottrell, Ltd., Englewood, Colorado.
RECALLED BY Manufacturer, by telephone beginning on May
30, 1997, followed by letter. Firm-initiated
recall ongoing.
DISTRIBUTION Nationwide, Canada, South Africa.
QUANTITY 316 cases (1,896 boxes) plus 6 individual
boxes were distributed.
REASON The specification for seal strength has not
been met which could result in the pouch
opening during use or storage thereby
compromising the sterility of the instrument
inside.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Coleman Aspiration Needles, used for tissue removal:
a) Catalog No. COL-ASPI, Coleman Aspiration Needle; b)
Catalog No. COL-ASPB, Coleman Body Aspiration Needle.
Recall #Z-749/750-7.
CODE All units.
MANUFACTURER Kolster Methods, Inc., Anaheim, California.
RECALLED BY Byron Medical, Tucson, Arizona, by letter on or
about June 20, 1997. Firm-initiated recall
ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY a) 408 units; b) 39 units were distributed.
REASON The cannula tip may separate from the cannula shaft
during use.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Narrow Platform Abutment Screws, for use with
3.3 mm narrow platform endosseous implant
fixtures:
a) Product #SDCA568: healing Abutment, 3mm high
b) Product #SDCA569: healing Abutment, 4mm high
c) Product #SDCA570: healing Abutment, 5mm high
d) Product #SDCA594: Standard Abutment, 3mm high
e) Product #SDCA595: Standard Abutment, 4mm high
f) Product #SDCA596: Standard Abutment, 5mm high.
Recall #Z-649/654-7.
Lot numbers: a) 523929, 524276, 524774
b) 523958, 524277, 524937

- c) 523972, 524278, 524956
- d) 524051, 525404, 526296, 526297
- e) 524078, 525403, 526346
- f) 524001, 525239, 526347.

MANUFACTURER Nobel Biocare AB, Gothenburg, Sweden.
 RECALLED BY Nobel Biocare USA, Inc., Westmont, Illinois, by letter dated April 17, 1997. Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide.
 QUANTITY 753 units were distributed; firm estimated that 50% of product remained on market at time of recall initiation.
 REASON Some are slightly oversize in the threaded area of the screw, and some resistance may be encountered when attempting to tighten the screw.

None Present
 Action Taken _____

NSN 6515 Nonstandard
 PRODUCT Acromioplasty Electrode Basic Kit, Catalog #9801B, used in the shoulder area when performing an Acromioplasty. Recall Z-628-7.
 CODE Lot numbers: 58738 and 60683.
 MANUFACTURER Linvatec, Inc., Largo, Florida.
 RECALLED BY Manufacturer, by letter dated April 29, 1997. Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide and England.
 QUANTITY 904 kits were distributed.
 REASON Some kits may contain a Meniscectomy Electrode instead of the labeled Acromioplasty Electrode.

None Present
 Action Taken _____

NSN 6515 Nonstandard
 PRODUCT Force Argon II Gas Delivery System (includes regulator)
 regulator) GR200 Pressure Regulator (for second argon bottle, used to provide energy delivery for argon-enhanced electrosurgery. Recall #Z-629/630-7.
 CODE Force Argon II System, Serial Nos. G6L101U through G7D160U; GR200 Regulator, Lot Nos. PCA563-03, 97095322, 9705322G, 9705323.
 MANUFACTURER Tescom, Minneapolis, Minnesota (regulator unit).
 RECALLED BY Valleylab, Inc., Boulder, Colorado, by telephone on May 2, 1997, followed by fax with confirming letters sent on May 2, 1997. Firm-initiated

recall ongoing.
 DISTRIBUTION International.
 QUANTITY 3 units.
 REASON Under certain conditions, the high pressure regulator may fail and cause the hose on the low pressure side of the regulator to rupture, which could cause injury to patients, surgical personnel or service technicians.

None Present
 Action Taken _____

NSN 6515 Nonstandard
 PRODUCT Sencicare Non-Sterile Medical Examination Gloves, powder free. Recall #Z-632-7.
 CODE Catalog #484302A, Lot #0121637, Sublot #63753N (on individual boxes).
 MANUFACTURER Maxxim Medical, Inc., Los Gatos, California.
 RECALLED BY Manufacturer, by letter on April 16, 1997.
 Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide.
 QUANTITY 819 cases of lot #0121637 and 59 cases of sublot #63753N were distributed.
 REASON The gloves are mislabeled as "Powder Free," which indicates the gloves do not contain powder. The gloves appear to have powder dusted on the interior surface.

None Present
 Action Taken _____

NSN 6520 Nonstandard
 PRODUCT Rubber Dam Clamp and Rubber Dam Clamp Kits:
 a) Ivory Brand Rubber Dam Clamp:
 Product Code
 b) Ivory Brand Rubber Dam Complete Kit,
 c) Ivory Brand Rubber Dam Starter Kit
 Recall #Z-655/657-7.

CODE	Product Code	Type	Lot Numbers
	57322	3	C6, Y6
	57324	4	C6, A6, P6
	57328	7	C6,A6, M6
	57528	W7	A6
	57330	7A	C6
	57336	8A	A6, M6, Y6
	57536	W8A	C6, L6, M6, R6
	57522	W3	L6, M6
	57348	12A	C6, A6
	57352	13A	C6, A6, M6

57356 14A C6, L6, A6, M6
 57556 W14A C6, A6, Y6
 57843 2T A6.

b) Product Code 57966,
 Lot Nos. 082996, 111196, and 111196A;
 c) Product Code 57968,
 Lot Nos. 0929396, 100996 and 120396.

MANUFACTURER Heraeus Kulzer, Inc., South Bend, Indiana.
 RECALLED BY Manufacturer, by letter March 19, 1997.
 Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide and Canada.
 QUANTITY 57,890 units were distributed.
 REASON Some clamps have broken during initial use or
 after a few uses.

None Present
 Action Taken _____

NSN 6550 Nonstandard
 PRODUCT Chlamydia Stat Pak, a rapid, visual assay for
 the detection of Chlamydia trachomatis antigen
 in endocervical, urethral, or male urine
 specimens. Recall #Z-666-7.
 CODE Lot #CH031397 EXP 2/28/99.
 MANUFACTURER Chembio Diagnostic Systems, Inc., Medford, New
 York.
 RECALLED BY Manufacturer, by telephone on April 30, 1997,
 followed by letter on May 1, 1997. Firm-initiated
 recall ongoing.
 DISTRIBUTION Massachusetts, Russia, Egypt, Jamaica.
 QUANTITY 9,040 paks were distributed.
 REASON The cassette has a shortened "lip" for holding
 the test membrane in place, making it
 difficult to read the results.

None Present
 Action Taken _____

NSN 6550 Nonstandard
 PRODUCT Vitros Hb DT Slides, used to measure the concentration
 of hemoglobin in blood.
 Recall #Z-563-7.
 CODE Vitros Hb DT Slides, Catalog No. 125 1453,
 GEN 75 - All lots starting with 2175-00052-xxxx,
 GEN 76 - All lots starting with 2176-00056-xxxx;

MANUFACTURER GEN 77 - All lots starting with 2177-00057-xxxx.
Johnson & Johnson Clinical Diagnostics, Inc.,
Rochester, New York.
RECALLED BY Manufacturer, by letter dated March 31, 1997.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 23,520 boxes (25 slides per box) were distributed.
REASON The hemoglobin results were biased to the reference
method.

None Present
 Action Taken _____

NSN 6550 Nonstandard
PRODUCT Confide HIV Home Test Kit - Federal Express
Mailers. Recall #B-855-7.
CODE None.
MANUFACTURER Direct Access Diagnostics (DAD), Bridgewater, New
Jersey.
RECALLED BY Manufacturer, by issuing revised instructions on
February 19, 1997, and by telephone beginning on
March 7, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 76,872 mailers were distributed.
REASON Federal Express mailer packages were incorrectly
attached to a competitor firm's packaged product
and distributed.

None Present
 Action Taken _____

CLASS III RECALLS:

NSN 6505 Nonstandard
PRODUCT Baxter's Hemofil M (Antihemophilic Factor
(Human) Method M Monoclonal Purified).
Recall #B-912-7.
CODE Lot numbers: 2935E075AA, 2935E076AA,
2935E097AA, 2935M004AA, 2935M005AA, 2935M016AA,
2935M017AA,
Foreign distribution: 2935E096AA.
ARC LOTS 29356071AA, 29356072AA.
MANUFACTURER Baxter Healthcare Corporation, Glendale,
California.
RECALLED BY Manufacturer, by letter on May 24 and 27, 1997,
and by fax on May 25, 1997. Firm-initiated
recall ongoing.
DISTRIBUTION Nationwide and international.

QUANTITY 31,303 vials were distributed.
REASON Baxter's Antihemophilic Factor recorded temperature deviations (lower validated temperatures) during solvent detergent viral inactivation treatment.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Sedapap Tablets, (50 mg butalbital/650 mg, Acetaminophen) packaged in bottles of 100,Rx, indicated for the relief of tension headaches. Recall #D-177-7.
CODE Lot numbers: S609 and S610.
MANUFACTURER Graham Laboratories, Hobart, New York.
RECALLED BY Merz Pharmaceuticals, Greensboro, North Carolina, by letter on April 23, 1997. Firm-initiated recall ongoing.
DISTRIBUTION North Carolina, South Carolina, Georgia, Florida, Alabama, Mississippi, Virginia, West Virginia, Tennessee.
QUANTITY 4,636 bottles of lot S609 and 4,829 bottles of lot S610 were distributed; firm estimated that 3,363 bottles remained on market at time of recall initiation.
REASON Discoloration.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Tussex-DM Expectorant Cough Suppressant, alcohol free, (100 mg guaifenesin/15 mg dextromethorphan), in 2 fluid ounce bottles. Recall #D-179-7.
CODE Lot numbers: 555-215, 55-334, 56-201.
MANUFACTURER Ferndale Laboratories, Inc., Ferndale, Michigan.
RECALLED BY Manufacturer, by letter issued on April 22, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Alabama, Arizona, California, Colorado, Connecticut, Delaware, Illinois, Indiana, Louisiana, Michigan, Missouri, New York, North Carolina, Ohio, Tennessee, Texas, Virginia, West Virginia, Wisconsin
QUANTITY 38,428 bottles were distributed.
REASON Ingredient non-uniformity.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Recovered Plasma. Recall #B-758-7.
CODE Unit numbers: 17033-9644, 28-29-2509, 17032-1780,
17178-2371, 28105-7910, 28105-9152,
28106-2227.
MANUFACTURERS United Blood Services, San Angelo, Texas;
United Blood Services, McAllen, Texas.
RECALLED BY Blood Systems, Inc., Scottsdale, Arizona, by
letters dated May 30 or 31, 1996.
Firm-initiated recall ongoing.
DISTRIBUTION Texas, Florida, Switzerland.
QUANTITY 7 units were distributed.
REASON Blood products tested negative for the
antibody to the human T-lymmphotropic virus
type 1 (anti-HTLV-I), but were collected from
donors who previously tested repeatedly

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Fraction IV-1 Paste (Plasma Fraction Intermediate).
Recall #B-744-7.
CODE Lot #963002.
MANUFACTURER V.I. Technologies, Inc. (VITEX), also konwn as
Melville
Biologicals, Inc., Melville, New York.
RECALLED BY Manufacturer, by telephone on August 23, 1996,
followed
by letter on March 25, 1997. Firm-initiated recall
ongoing.
DISTRIBUTION North Carolina.
QUANTITY 42.1kg was distributed.
REASON Fractionated products with detectable levels of
ethylene glycol were distributed.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT SoloPak Magnesium Sulfate Injection USP, 50%,
in 2 ml vials, preservative free, Rx
parenteral anticonvulsant. Recall #D-198-7.
CODE Lot #951140 EXP 11/98.
MANUFACTURER SoloPak Laboratories, Inc., Elk Grove Village,
Illinois.
RECALLED BY Manufacturer, by letter dated May 12, 1997.

Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 175,550 vials were distributed; firm estimated that 1% of product remained on market at time of recall initiation.
REASON Product exceeds pH specifications in stability testing.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT SoloPak Heparin products, the lock flush solution is used for maintenance of patency of indwelling intravenous catheters designed for intermittent injection therapy or blood sampling, and not to be used for anticoagulant therapy, while the heparin sodium injection is used for anti-coagulant:
a) Heparin Lock Flush Solution, USP, 100 u/mL, Preservative Free, 1 mL fill in 2 Ml single dose vials and 2 and 5 mL single dose vials;
b) Heparin Lock Flush Solution, USP, 10 mL, Preserved, 10 and 20 ml multiple dose vials
c) Heparin Lock Flush Solution, Preserved, 100 u/mL, 10 and 30 mL multiple dose vials
d) Heparin Sodium Injection, USP, Preserved, porcine, 1000 u/mL, in 10 and 30 mL multiple dose vials. Recall #D-200/203-7.

CODE All lots within expiration date.
MANUFACTURER SoloPak Laboratories, Inc., Elk Grove Village, Illinois.
RECALLED BY Manufacturer, by letter dated May 14, 1997.
DISTRIBUTION Firm-initiated recall ongoing.
QUANTITY Nationwide and Canada.
12,984,850 vials were distributed; firm estimated that 25% of the product remained on market at time of recall initiation.
REASON Product contains visible particulate matter.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Thyrolar Tablets (Liotrix Tablets, USP), in bottles of 100, used in the treatment of the thyroid: a) 1/4 mg; b) < mg; c) 1 mg; d) 2 mg; e) 3 mg. Recall #D-204/208-7.
CODE All lots received since September 1996 held unrefrigerated.
MANUFACTURER Forest Pharmaceuticals, Inc., St. Louis, Missouri.

RECALLED BY Giant of Maryland, Inc., Landover, Maryland,
by voice mail on May 8, 1997. Firm-initiated
recall ongoing.
DISTRIBUTION Maryland, Virginia, Pennsylvania, New Jersey,
Delaware.
QUANTITY a) 13 bottles; b) 7 bottles; c) 149 bottles;
d) 74 bottles; e) 23 bottles were distributed.
REASON Improper temperature storage.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Bio-Safe Antibacterial Lotion (Triclosan 0.3%),
in 2 fluid ounce plastic bottles.
Recall #D-184-7.
CODE Lot #12 EXP 98 6887.
MANUFACTURER Stanford Personal Care Manufacturing, Saugus,
California.
RECALLED BY Bio-Safe Skin Products, Milwaukee, Oregon, by
letter dated April 14, 1997, followed by
telephone. Firm-initiated recall ongoing.
DISTRIBUTION Arizona, California, Hawaii, Oregon, Washington
state, Wisconsin.
QUANTITY 798 bottles were distributed.
REASON Separation of lotion.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Aspirin Free Excedrin Extra Strength Caplets, in
bottles of 100, OTC pain reliever.
Recall #D-185-7.
CODE Lot #EREQ6M1AV, Case Code 0893, EXP 5/99.
MANUFACTURER Bristol-Myers Products, Morrisville, North
Carolina.
RECALLED BY Bristol-Myers Products, A Bristol-Myers Squibb
Company, Hillside, New Jersey, by letter dated
January 23, 1997. Firm-initiated recall
ongoing.
DISTRIBUTION New Jersey, Georgia, California, Illinois,
Hawaii.
QUANTITY 1,655 cases (24 bottles per case) were
distributed.
REASON Labeling -- Carton incorrectly lists aspirin as
ingredient.

None Present

[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Benadryl Itch Stopping Gel, 2%, Extra Strength
in 4 ounce containers. Recall #D-187-7.
CODE Lot #'S 868261 and 86826LX as open stock items,
and the Benadryl poison ivy display lot 00836Y,
01236Y, 01336Y, and 01336YA.
Lot 868261 was packaged into 60.552 containers
each containing 4 oz. of the gel and bearing the
item code 17160. The entire lot of the 4 oz
containers was shipped to the recalling firms
customer service center to be packaged as 1,260
units of the Poison Ivy 48-Pie E Wing Unit
display and the displays were assigned lots
numbers 00836Y, 01136Y, 01236Y, and 01336YA.
Part of these displays, 134 units, were later
broken down to generate open stock items and
were assigned the lot number 868261X. Each
individual container does however bear the lot
number 868261.
MANUFACTURER Paco Pharmaceutical Services, Lakewood, New
Jersey.
RECALLED BY Warner-Lambert, Consumer Healthcare Division,
Morris Plains, New Jersey, by letter dated April
14, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 7,650 units were distributed.
REASON Product fails to meet zinc acetate content
specifications through shelf-life (stability).

[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT a) Red Blood Cells; b) Platelets; c) Recovered
Plasma. Recall #B-877/879-7.
CODE Unit numbers: a)11045-9363, 11043-3315, 11034-9969;
b) 11045-9363, 11043-3315, 11034-9969; c) 11034-9969,
11043-3315.
MANUFACTURER United Blood Services, El Paso, Texas.
RECALLED BY Blood Systems, Inc., Scottsdale, Arizona, by
letters dated February 21, 1997, and May 2,
1997. Firm-initiated recall ongoing.
DISTRIBUTION Texas, New Mexico, New York, North Carolina.
QUANTITY a) 3 units; b) 3 units; c) 2 units were
distributed.
REASON Blood products were collected from a donor who
had previously self-excluded.

[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Mexiletine Hydrochloride Capsules, 250 mg, Rx orally active antiarrhythmic used for the treatment of documented life-threatening ventricular arrhythmias, in 100 capsule bottles. Recall #D-228-7.
CODE Lots 100860A, 100861A, 101262A, 104912C.
MANUFACTURER Novopharm Ltd., Toronto, Canada.
RECALLED BY Novopharm USA, Inc., Schaumburg, Illinois, by letter dated July 9, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 2,401 bottles were distributed; firm estimated that 25 percent of product remained on market at time of recall initiation.
REASON Incorrect labeling -- Some bottles of 250 mg capsules are labeled as containing 150 mg capsules.

[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Fresh Frozen Plasma. Recall #B-1001-7.
CODE Unit numbers: 4416104, 4422379, 4422395,
4434783 6740379 6740383 7014364
7014369 7014371 7014372 7014376
7074039 7188153 7192601 7195848
7229463 7247817 7296027 7351673
7369616 7376155 7376914 7378155
7386207 7389603 7394208 7396337
7581829 7591522 7591546 7635770
7638517 7638526 7638533 7638538
7638756 7648751 7652746 7652754
7655203 7655206 7655210 7665257.
MANUFACTURER New York Blood Services, also known as New York Blood Center, New York, New York.
RECALLED BY Manufacturer, by letter dated January 9, 1997. Firm-initiated recall ongoing.
DISTRIBUTION New York and New Jersey.
QUANTITY 43 units collected from 3/95 to 11/96 were distributed.
REASON Blood products contain the preservative Adsol but not labeled as containing that preservative.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Lithobid (Lithium Carbonate extended release tablets, 300 mg, packaged in bottles of 100 and 1000, Rx used for the treatment of depression and bipolar disease. Recall #D-217-7.
CODE Lot numbers: 86864 (100s) and 86848 (1000s).
MANUFACTURE Solvay Pharmaceuticals, Baudett, Minnesota.
RECALLED BY Solvay Pharmaceuticals, Marietta, Georgia, by telephone on April 17, 1997 and by letter on May 23, 1997. Firm-initiated recall ongoing.
DISTRIBUTIO Nationwide.
QUANTITY 13,917 100-tablet bottles and 1,432 1000-tablet bottles were distributed.
REASON Dissolution failure (stability).

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Lithium Carbonate Tablets, USP, 300 mg, packaged in bottles of 100, Rx prescribed as remedial and/or maintenance drug therapy for the treatment of individuals diagnosed with manic episodes characterizing Bipolar Disorders. Recall #D-225-7.
CODE Lot #961458 EXP 6/1/98.
MANUFACTURE Roxane Laboratories, Inc., Columbus, Ohio.
RECALLED BY Manufacturer, by letter on June 16, 1997. Firm-initiated recall ongoing.
DISTRIBUTIO Nationwide.
QUANTITY 9,455 bottles were distributed; firm estimated that 20% of product remained on market at time of recall initiation.
REASON Product fails dissolution specification (stability).

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Histalet Forte Tablets, antihistamine -decongestant(Phenylpropanolamine HCl 50 mg/Pyrilamine Maleate 25 mg/Phenylephrine HCl 10 mg/Chlorpheniramine Maleate 4 mg), packaged in 20, 100 and 250 tablet bottles. Recall #D-226-7.

CODE Lot numbers: F960551A - 250 tablet bottles
 F960551B - 100 tablet bottles X960778A - 20 tablet
 bottles ** X960778B - 250 tablet bottles
 X960778C - 100 tablet bottles
 **repackaged into bottles of 100's.
 MANUFACTURER Mikart, Inc., Atlanta, Georgia.
 RECALLED BY Manufacturer, by letter on May 20, 1997.
 Firm-initiated recall ongoing.
 DISTRIBUTION Alabama, Arizona, California, Florida,
 Massachusetts, Maryland, Missouri, Mississippi,
 North Carolina, New Jersey, Ohio, Oklahoma, Texas.
 QUANTITY Lot F960551A - 376 bottles were shipped
 Lot F960551B - 3727 bottles were shipped
 Lot X960778A - 9919 bottles were shipped
 Lot X960778B - 259 bottles were shipped
 Lot X960778C - 2160 bottles were shipped.
 REASON Product failed content uniformity (validation).

None Present
 Action Taken _____

NSN 6505 Nonstandard
 PRODUCT 1% Lidocaine HCl Injection, USP, 10 mg/ml, 50 ml
 multiple dose vials held in shelf packs of 25 vials,
 Rx SVP for production of local or regional
 anesthesia. Recall #D-227-7.

CODE Lot #23-198-DK.
 MANUFACTURER Abbott Laboratories, Rocky Mount, North Carolina.
 RECALLED BY Abbott Laboratories, Hospital Products Division,
 Abbott Park, Illinois, by letter dated June 26,
 1997. Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide and The Netherlands.
 QUANTITY 180,250 vials were distributed; firm estimated that
 20% of product remained on the market at time of
 recall initiation.
 REASON Mispackaged -- Correctly labeled 2% vial packaged in
 1% labeled shelf pack.

None Present
 Action Taken _____

NSN 6515 Nonstandard
 PRODUCT Pressure monitoring kits, lines, single put-up
 flush devices:
 (a) Pressure Monitoring Kits
 (b) Pressure Monitoring Lines
 (c) Single Put-Up Flush Devices
 (d) Single Put-Up Monitoring Lines
 (e) Extension Sets
 (d) CDXPress Transducers.

Recall #Z-572/577-7.
CODE Products manufactured from 12/26 to 3/97.
MANUFACTURER Medical, Argon Division, Athens,
Massachusetts.
RECALLED BY Maxxim Medical, Argon Division, Athens, Texas,
by letter, March 28, 1997. Firm-initiated
recall ongoing.
DISTRIBUTION Nationwide and Canada.
QUANTITY 338,883 items were distributed.
REASON The monitoring lines are separating from
connectors and flushing devices.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT LifePort Infuse-a-Port Implantable Port
Systems:
(a) Snap-Lock™ MacroPort™ Arterial Access
System, Catalog No. 39514,
(b) Snap-Lock™ MicroPort™ Arterial Access
System, Catalog No. 39615.
Recall #Z-578/579-7.
CODE Lot Nos. (a) 13914, 14106, 14190, 13973,
13845; (b) 13282, 13757.
MANUFACTURER Strato/Infusaid, Inc., Norwood,
Massachusetts.
RECALLED BY Manufacturer, by telephone between April 30,
1997 and May 1, 1997. Firm-initiated recall
ongoing.
DISTRIBUTION Missouri, New York, Indiana, Colorado,
Massachusetts, Texas, Florida, Alabama,
Connecticut, international.
QUANTITY 2,927 units were distributed.
REASON The catheters or ports of certain lots of
arterial Infuse-a-ports may contain stainless
steel spheres which could result in the
metallic spheres flushing from the catheter or
port.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Innovasive Retractor Blade (Arm),
20 mm x 80 mm, used in orthopedic procedures.
Recall #Z-583-7.
CODE Catalog #2513, Lot #10664.
MANUFACTURER Innovasive Devices, Inc., Marlborough,

RECALLED BY Massachusetts.
 Manufacturer, by letter dated May 2, 1997.
 Firm-initiated recall ongoing.
DISTRIBUTION Oregon, South Carolina, Massachusetts, Texas.
QUANTITY 30 units (15 sets) were distributed.
REASON The arm length was found to measure 65 mm
 instead of the 80 mm as labeled.

[] None Present
[] Action Taken _____

NSN 6515 Nonstandard
PRODUCT Pressure Sentinel Intramedullary Flexible
 Reamers:

1. Catalog No. 00-2228-005-00
2. Catalog No. 00-2228-005-05
3. Catalog No. 00-2228-006-00
4. Catalog No. 00-2228-006-05
5. Catalog No. 00-2228-007-00
6. Catalog No. 00-2228-007-05
7. Catalog No. 00-2228-008-00
8. Catalog No. 00-2228-008-05
9. Catalog No. 00-2228-009-00
10. Catalog No. 00-2228-009-05
11. Catalog No. 00-2228-010-00
12. Catalog No. 00-2228-010-05
13. Catalog No. 00-2228-011-00
14. Catalog No. 00-2228-011-05
15. Catalog No. 00-2228-012-00
16. Catalog No. 00-2228-012-05
17. Catalog No. 00-2228-013-00
18. Catalog No. 00-2228-013-05
19. Catalog No. 00-2228-014-00
20. Catalog No. 00-2228-014-05
21. Catalog No. 00-2228-015-00
22. Catalog No. 00-2228-015-05
23. Catalog No. 00-2228-016-00
24. Catalog No. 00-2228-016-05
25. Catalog No. 00-2228-017-00
26. Catalog No. 00-2228-017-05
27. Catalog No. 00-2228-018-00
28. Catalog No. 00-2228-018-05
29. Catalog No. 00-2228-019-00
30. Catalog No. 00-2228-019-05
31. Catalog No. 00-2228-020-00
32. Catalog No. 00-2228-020-05
33. Catalog No. 00-2228-021-00
34. Catalog No. 00-2228-021-05
35. Catalog No. 00-2228-022-00.

Recall #Z-590/624-7.

CODE All lot numbers.

MANUFACTURER Zimmer, Inc., Warsaw, Indiana.
RECALLED BY Manufacturer, by E-mail on February 7, 1997.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide, Canada, Singapore.
QUANTITY Approximately 1,285 units were distributed.
REASON Cracks were found on the cutting tips.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Comfortec Disposable pH Probes, used for monitoring
pH levels in the esophagus. Recall #Z-571-7.
CODE Catalog numbers: NIS, NID5, NID10, NID15, NID21,
IIS, IID5, IID10, IID15, IID21.
Lot numbers: 1996 Lots: 601, 602, 603, 604, 605,
606, 607, 608,609, 610, 611, 612.
1997 Lots: 701, 702, 703, 704.
MANUFACTURER Alpine Biomed Corporation, Santa Ana, California.
RECALLED BY Sandhill Scientific, Inc., Highlands Ranch, Colorado,
by letter sent on April 29, 1997. Firm-initiated
recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY Firm estimated that 400-500 probes remained at
customer
locations at time of recall initiation.
REASON A precipitate may form on the probe connector leads
and
break the signal path between the probe and the data
logger, resulting in loss of signal.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Stainless Steel CHS Keyed Lag Screw - Super:
a) Part No. 1327-46-000
b) Part No. 1327-48-000
c) Part No. 1327-50-000
d) Part No. 1327-52-000
e) Part No. 1327-54-000
f) Part No. 1327-56-000
g) Part No. 1327-58-000
h) Part No. 1327-60-000
i) Part No. 1327-62-000
Recall #Z-728/736-7.
CODE Lot numbers: a) QW235; b) QW236, QW377;
c) QW237, QW378; d) QW238, QW379;
e) QW239, QW478, QW519;

- f) QW240, QW381, QW479, QW529;
- g) QW241, QW382, QW480;
- h) QW242, QW383, QW481, QW522;
- i) QW243, QW384, QW523.

MANUFACTURER RECALLED BY Depuy Ace Medical Company, El Segundo, California. Manufacturer, by telephone on April 14, 1997, followed by fax on April 17, 1997 and mailed on April 18, 1997. Firm-initiated recall ongoing.

DISTRIBUTION California, Texas, Florida, Ohio, Virginia, Illinois.

QUANTITY 306 pieces were distributed.

REASON The 16mm head diameter screws are labeled as being 13mm head diameter screws.

None Present
 Action Taken _____

NSN 6515 Nonstandard

PRODUCT Siemens 12 Lead ECG Patient Cable and Cable Kit, used with the Siemens Cathcor Equipment an ECG recording device:

- a) 12 Lead ECG Patient Cable, Part No. 0899300.
- b) 12 Lead ECG Cable Kit, Part No. 0899399.

Recall #Z-741/742-7.

CODE Lot #R0823.

MANUFACTURE ConMed Corporation, Utica, New York.

RECALLED BY Siemens Medical Systems, Inc., Danvers, Massachusetts, by letters on May 23, 1997, and June 5, 1997. Firm-initiated recall ongoing.

DISTRIBUTIO Nationwide.

QUANTITY 184 cables were distributed.

REASON The indicator tabs for the Left Arm (LA) and Left Leg (LL) leads are reversed.

None Present
 Action Taken _____

NSN 6515 Nonstandard

PRODUCT Microaire Pulse Lavage Tube Sets and Pulse Lavage Hip Sets, used with the Pulse Lavage Handpiece 4740-000, a precision instrument for debriding bone surfaces as well as cleansing trauma and other soft tissue wounds. Recall #Z-705/708-7.

CODE

	Product Number	Lot Number
a)	4740-060	129624156
	4740-060	019724464
	4740-060	029725355
b)	4740-061	119623581

4740-061 119623582
 4740-061 119623583
 4740-061 019724833
 4740-061 029724834
 4740-061 029725487, 039725776
 c) 4740-062 119623858
 4740-062 129623048
 4740-062 129624155
 4740-062 129624395
 4740-062 019724465
 4740-062 039725707

d) 5600-70 DePuy Lot NO. R98AK4000
 DePUY Product MicroAire Lot No. 019724466.

MANUFACTURER Microaire Surgical Instruments, Charlottesville, Virginia.
 RECALLED BY Manufacturer, by letters dated April 15 and 28, 1997. Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide and international.
 QUANTITY 1,389 tubing set units and 197 hip set units were distributed.
 REASON The devices are subject to separation at the joint between the nose connection and the pump body of the product which could result in the nozzle falling into the surgical field.

[] None Present
 [] Action Taken _____

NSN 6515 Nonstandard
 PRODUCT Anesthesia Gas Sampling Tee Connector, Part No. 92002, and Anesthesia Circuits which Contain the Gas Sampling Tee Connector:
 a) Ohmeda brand Gas Sampling Straight Tee (Plastic);
 b) SpaceLabs Medical brand TRU-LINK DISPOSABLE ANESTHETIC AGENT SAMPLE LINE WITH GAS SAMPLING TEE for use with 90518 Multigas Analyzer;
 c) SpaceLabs Medical brand TRU-LINK DISPOSABLE ANESTHETIC AGENT SAMPLE LINE WITH GAS SAMPLING TEE for use with 90518 Multigas Analyzer;
 d) Gibeck brand Gas Sampling
 e) Gibeck brand Gas Sampling
 f) Gibeck brand Mass Spec Straight Tee
 g) Gibeck brand Gas Sampling Tee
 h) Gibeck brand Adult Anesthesia Breathing Circuit
 i) Gibeck brand Pediatric Anesthesia Breathing Circuit
 j) Gibeck brand Adult Anesthesia Breathing Circuit
 k) Gibeck brand Gas Sampling Tee with Luer
 l) Gibeck brand Pediatric Anesthesia Breathing Circuit
 m) Gibeck brand Adult Anesthesia Breathing Circuit

- n) Gibeck brand Mass Spec Tee w/Cap Put Label (Criticare)
 - o) Gibeck brand Gas Sampling Tee & Cap Put Label (Datex).
- Recall #Z-711/725-7.

CODE

- a) Product No. 6027-0000-019; Lot No. M027794.
- b) Product 015-0312-00; Lot No. M027658.
- c) Product No. 015-0313-00; Lot No. M027659.
- d) Product No. 126213-BQW; Lot No. M028791.
- e) Product No. 12820, Lot Nos. M029039, P003583, and P003612.
- f) Product No. 12820B; Lot No. M027901.
- g) Product No. 12820-150, Lot Nos. M028219 and M028360.
- h) Product No. 16303-742; Lot Nos. C033964, C034071, C034157, and C034247.
- i) Product No. 16511-742; Lot No. C034073.
- j) Product No. 173232-BPG; Lot No. C033735.
- k) Product 24432; Lot No. M028809.
- l) Product 304-0002-710; Lots No. C034015 and C034262.
- m) Product No.304-0001-724; Lot Nos. C034229, C034032, and C034401.
- n) Product No. 41439B001; Lot No. M027488.
- o) Product No. 73385; Lot No. M028990.

MANUFACTURER
RECALLED BY

Gibeck, Inc., Indianapolis, Indiana.\n
Manufacturer, by letter on April 21, 1997. Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY

Nationwide and international.
53,800 connectors were distributed.

REASON

The gas sampling tee connector was observed to be partially occluded by a thin molded membrane inside the connector.

[] None Present
[] Action Taken _____

NSN
PRODUCT

6520 Nonstandard
Injectable Rx dental (local anesthetics sold in vacuum-sealed cans of 50 single use cartridges (capsule) each containing 1.8 ml solution:
a) Carbocaine 2% (36 mg) with Neo-Cobefrin 1:2000 Injection (Mepivacaine Hydrochloride/Levonordefrin Injection, USP);
b) Lidocaine HCL 2% and Epinephrine 1:50,000 Injection (Lidocaine Hydrochloride and Epinephrine Injection USP)
c) Lidocaine HCL 2% and Epinephrine 1:100,000

Injection

Injection,USP)

(Lidocaine Hydrochloride and Epinephrine

d) Marcaine 0.5% (9 mg) with Epinephrine 1:200,000 Injection (Bupivacaine Hydrochloride and Epinephrine Injection, USP). (Note: Product is labeled Cook-Waite (trademark) Marketed by Eastman Kodak Company, Dental Products, manufactured by Sanofi Winthrop, Inc., New York, New York.) Recall #D-230/233-7.

CODE Lot numbers: a) C850RB EXP 2/99 and C520RA EXP 1/99;
1/99, b)C860RB EXP 2/99; c) C545RB EXP 2/99, C565RA EXP

C570RB EXP 2/99; d) C565RB EXP 8/99.

MANUFACTURER Sanofi Winthrop Pharmaceuticals, McPherson, Kansas (contract manufacturer)

RECALLED BY Eastman Kodak Company, Rochester, New York, by letter dated April 30, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and Puerto Rico.

QUANTITY 35,390 cans were distributed.

REASON Product packaged in cans without vacuum to assure potency throughout labeled expiration date.

[] None Present

[] Action Taken _____

NSN 6540 Nonstandard

PRODUCT Hydron Proactive 55 (Ocufilecon D) Disposable Contact Lenses, in blister package that is put into a box. Recall #Z-625-7.

CODE 2400516503, 2400516937, 2400516838, 2400516210, 2400516747, 2400517385, 2400516638, 2400517066, 2400516936, 2400516946, 2400516592, 2400516805, 2400517482, 2400516738, 2400516522, 2400516996, 2400517202, 2400516128, 2400516878, 2400516503.

MANUFACTURER Ocular Science/American Hydron, San Francisco, California.

RECALLED BY Manufacturer, by telephone and by letter on April 24, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 1,577 boxes are subject to recall.

REASON The wrong label on the blister is for the HYDRON PROACTIVE FW (POLYMACON) contact lens, however, the lens in the blister is a HYDRON PROACTIVE 55 contact lens.

[] None Present

[] Action Taken _____

NSN 6540 Nonstandard

PRODUCT 2.5 mm Disposable Optical Valvulotome, Model #A5205, used for valve incision during in-situ

saphenous vein arterial bypass procedures. Recall #Z-639-7.

CODE Lot numbers: 95L268, R5N009, 96B137.

MANUFACTURER Applied Medical Resources, Laguna Hills, California.

RECALLED BY Manufacturer, by telephone followed by fax on August 1, 1996. Firm-initiated recall ongoing.

DISTRIBUTION Florida, Illinois, New Mexico, Spain.

QUANTITY 9 units were distributed.

REASON The product labeled as 2.5 mm disposable angioscopes but contain 2.5 mm disposable optical valulotomes.

None Present
 Action Taken _____

NSN 6550 Nonstandard

PRODUCT (a) Coulter HIV-1 p24 Antigen Neutralization Kit; (b) Coulter HIV-1 p24 Antigen Assay; (c) Coulter HIV-1 p24 Antigen ELISA Test System. Recall #B-564/566-7.

CODE All lots,

MANUFACTURER Coulter Corporation, Miami, Florida.

RECALLED BY Manufacturer, by letter February 10, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 25,187 kits were distributed.

REASON The reconstituted Positive Antigen Reagent product may not remain stable over the period indicated in the product labeling.

None Present
 Action Taken _____

NSN 6550 Nonstandard

PRODUCT Bacto Leptospira Enrichment EMJH, Product No. 0795-73, for in-vitro cultivation of Leptospira. Recall #Z-662-7.

CODE Lot Nos. 72207JA, 72208JA, 72209JA, 73283JA, 73289JA, 74265JA, 74370JA, 74754JA, 75099JA, 76485JA, 79680JA, 80758JA, 80828JA, 81666JA, 84380JB, 85611JA, 86735JA, 87323JA, 87579JA, 88532JA, 88533JA, 88534JA, 88535JA, 91980JA, 92150JA, 92152JA, 92153JA, 95796JA, 95843JA, 98857JA, 100638JB, and 100639JA.

MANUFACTURER Difco Laboratories, Detroit, Michigan.

RECALLED BY Difco Laboratories, Livonia, Michigan, by letters dated April 26, 1997, and May 8, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and international.

QUANTITY 1,781 packages were distributed.

REASON The product is contaminated with Leptospira

[] None Present
[] Action Taken _____

NSN 6550 Nonstandard

PRODUCT Abbott HTLV-1 2.0 EIA diagnostic Kit, Human
T-Lymphotropic Virus Type 1. Recall #B-735-7.

CODE Lot #25685M301 EXP 7/11/97.

MANUFACTURER Abbott Laboratories, Diagnostic Division,
Abbott Park, Illinois.

RECALLED BY Manufacturer, by telephone on April 25, 1997,
and by letter dated April 28, 1997. Firm-initiated
recall ongoing.

DISTRIBUTION Arizona, Louisiana, New York, North Carolina,
Oklahoma, Pennsylvania,
Rhode Island, South Dakota, Texas.

QUANTITY 2 kits and 237 bulk tests were distributed.

REASON HTLV-1 2.0 coated bead bottles contain inappropriate
Corzyme beads.

[] None Present
[] Action Taken _____

NSN 6550 Nonstandard

PRODUCT Streptokinase Kabikinase, a sterile purified
preparation of bacterial protein elaborated by
group C B-hemolytic streptococci:

a) Streptokinase Kabikinase 250,000 IU;
b) Streptokinase Kabikinase 1,500,000 IU.

Recall #B-781/782-7.

CODE Lot numbers: a) 14476A51, 14476B51, 14476C51;
b) 14304A51, 14304D51.

MANUFACTURER Pharmacia AB, Stockholm, Sweden.

RECALLED BY Pharmacia & Upjohn Company, Kalamazoo, Michigan,
by letter dated May 5, 1997. Firm-initiated recall
ongoing.

DISTRIBUTION Nationwide.

QUANTITY Approximately 16,000 vials were distributed.

REASON Streptokinase Kabinase did not meet potency
specification throughout the labeled shelf-life.

[] None Present
[] Action Taken _____

NSN 6550 Nonstandard

PRODUCT TDx/TDxFLx Estriol Reagent Pack, List No.

9112-60, used with either Total Estriol Calibrators (lists 9112-01) or Free Estriol Calibrators (list 9118-01) in a Fluorescence Polarization Immunoassay (FPIA) in-vitro estriol or free estriol in human serum, plasma or urine. Recall #Z-738-7.

CODE Lot Nos. 22109Q100, 23635Q100, 25589Q100, and 26075Q100.

MANUFACTURER Abbott Health Products, Inc., Barceloneta, Puerto Rico.

RECALLED BY Abbott Laboratories, Diagnostics Division, Abbott Park, Illinois, by letter on July 2, 1997. Firm-initiated recall ongoing.

DISTRIBUTION California, Kentucky, Georgia, Illinois, Indiana, Louisiana, Maryland, West Virginia, Ohio, Pennsylvania, Texas, and international.

QUANTITY 1,226 reagents packs were distributed; firm estimated that 10 percent remained on market at time of recall initiation.

REASON Storage of the antibody S reagent for extended time at elevated temperatures can cause heat stressing which results in depressed millipolarization values and display of the printed error code "PO Too Small" during calibration.

None Present
 Action Taken _____

NSN 6550 Nonstandard
PRODUCT Quidel QuickVue Chlamydia Test, Catalog No.
B006. Recall #Z-739-7.
CODE Lot Nos. B006 J04501, B006 J04801, B006
J04802, B006 J06901, B006 J08001, B006 J09001,
B006 J10601, and B006 J11201.
MANUFACTURER Quidel Corporation, San Diego, California.
RECALLED BY Manufacturer, by telephone and by letter dated
May 21, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 1,809 (30 tests/kit) kits were distributed.
REASON Faint or no results are obtained with the
positive control solution.

None Present
 Action Taken _____
